JAN 2 9 2001

K003397

1 OF 2

510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Marcia J. Arentz** Senior Regulatory Associate Phone: (219) 371-4944 FAX: (219) 371-4940
Trade Name:	**Colles C Series Frame Sterile Pack**
Common Name:	External Fixation device
Classification:	**Class II** Device per 21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories.
Device Product Code:	Code: **87KTT** Appliance, Fixation, Nail/Blade/Plate combination, multiple component. No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.
Substantially Equivalent Device:	**Threaded Pins Self-Drilling** **K781251** **Colles Fixator** **K842768** **Mini-Fixator for Colles Fractures** **K982982**
Device Descriptions:	The Colles C Series Frame Sterile Pack is an external fixation device used in the treatment of fractures of the wrist. The system is comprised of half pins that are implanted through the skin attached to adjustable connecting rods that can apply traction. The kit also includes instrumentation required for the surgery.

510(k) Summary (continued)

Intended use:	For use in the fixation of distal fractures of the upper extremity. External fixation systems allow control of bone segments including angulation, rotation and displacement.
Indications for use:	Commuted, intra-articular distal radius fractures (Frykman-Classification III-VIII), Bilateral Colles' fracture, failed closed reduction with casting.
Substantial equivalence:	The Colles Fixator is the same device cleared in K842768. The pins are the same design and intended use as those cleared in K781251. The fixator and the pins are packaged together with instruments in a sterile package and are substantially equivalent to the Biomet Mini-Fixator for Colles Fractures cleared in K982982

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K003397
Trade Name: Colles C Series Frame Sterile Pack
Regulatory Class: II
Product Code: KTT
Dated: October 30, 2000
Received: November 1, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003397

Device Name: Colles Fixator

Indications for Use:

For use in the fixation of distal fractures of the upper extremity. External fixation systems allow control of bone segments including angulation, rotation and displacement.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003397